IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WALTER E. RYAN, JR., derivatively on behalf of JOHNSON & JOHNSON, Plaintiff, v. WILLIAM WELDON, MARY SUE COLEMAN, JAMES G. CULLEN, MICHAEL M.E. JOHNS, SUSAN L. LINDQUIST, ANNE MULCAHY, LEO F. MULLIN, WILLIAM D. PEREZ, CHARLES PRINCE and DAVID SATCHER, Defendants, and JOHNSON & JOHNSON, Nominal Defendant.	)	Civil Action No._____ **VERIFIED SHAREHOLDERS' DERIVATIVE COMPLAINT**

Plaintiff, Walter E. Ryan, Jr. ("Plaintiff"), brings this derivative complaint and alleges, upon information and belief, based on the investigation of his counsel, as follows:

INTRODUCTION

1. This shareholders' derivative action is brought in the right of, and for the benefit of, nominal defendant Johnson & Johnson ("JNJ" or the "Company")[1] against its management and Board of Directors (collectively referred to as the "Defendants"), all of whom authorized, or through their abdication of duty, permitted, and failed to disclose, JNJ's vast criminal and civil exposure in connection with multiple government investigations relating to JNJ's: 1) sales practices of certain products; 2) off-label marketing schemes; and 3) product recalls.

[1] Many of the wrongful acts and schemes alleged herein were directly performed by the Company's wholly-owned subsidiaries, such as Cordis Corporation, Janssen, L.P., Ortho-McNeil Pharmaceutical LLC and Scios, Inc. Unless otherwise noted, references to JNJ herein include the Company's subsidiaries.

2. As alleged herein, Defendants approved or failed to halt JNJ's schemes to:

(a) Violate the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), by paying Omnicare, Inc. ("Omnicare") to "push" physicians to prescribe certain medications.

(b) Illegally market certain medications "off-label;" and

(c) Ignore government investigations into the Company's Good Manufacturing Practices ("GMPs"), causing a massive product recall.

3. Further, Defendants never caused JNJ to disclose the existence of these practices in JNJ's annual proxy statements for 2008 and 2009.

4. Defendants have breached their fiduciary duties of care, good faith and loyalty, and have substantially damaged JNJ. Among other things, Defendants:

(a) Failed to ensure that the Company implemented adequate internal controls to prevent a variety of improper business practices, including controls over JNJ's marketing practices;

(b) Failed to cause the Company to implement adequate internal controls to prevent fraud relating to the reporting of JNJ's financial condition;

(c) Caused JNJ to issue materially false and misleading financial statements; and

(d) Failed to cause JNJ to implement adequate internal controls to prevent massive civil liabilities and product recalls.

5. Indeed, Defendants exposed Johnson & Johnson to numerous liabilities, including:

(a) Substantial civil liability because of illegal business practices;

(b) Damage to the Company's reputation within the market;

(c) A loss of financial goodwill;

(d) A loss of good will of JNJ's name and brand for the purposes of its banking activities;

(e) Damages to JNJ's reputation in the financial community, exposing itself, to, *inter alia*, loss of corporate client base;

(f) Substantial expenses resulting from costly investigations and defense costs;

(g) Damages and legal defense costs for consumer fraud class action litigation and *qui tam* litigation; and

(h) Substantial additional future costs to remediate its failed corporate governance processes and institutional operations.

JURISDICTION AND VENUE

6. This Court has jurisdiction over Plaintiff's claims asserted herein pursuant to 28 U.S.C. § 1332(a)(2) as Plaintiff and the Defendants are citizens of different States and the amount in controversy exceeds $75,000, exclusive of interest and costs. Plaintiff also asserts claims under Section 14(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. § 78n(a), and Rule 14a-9 promulgated thereunder, and jurisdiction is proper under 15 U.S.C. § 78aa and 28 U.S.C. § 1331. Further, this Court has supplemental jurisdiction pursuant to 28 U.S.C. §1367(a) over all other claims that are related to claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution. This action is not a collusive action designed to confer jurisdiction on a court of the United States that it would not otherwise have.

7. This Court has jurisdiction over each Defendant named herein because each is either a corporation that conducts business in and maintains operations in this District, or is an individual who has sufficient minimum contacts with this District so as to render the exercise of jurisdiction by the courts of this District permissible under traditional notions of fair play and substantial justice. All defendants are management or board members of a corporation organized under New Jersey law.

8. Venue is proper in this District pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. § 1391(b) and (e). Many of the acts charged herein, including the preparation and dissemination of materially false and misleading information to the investing public, occurred in substantial part in this District. Venue is also proper in this Court pursuant to 28 U.S.C. §1391(a) because: (a) JNJ maintains its principal place of business in the District; (b) one or more of the Defendants either resides in or maintains executive offices in this District; (c) a substantial portion of the transactions and wrongs complained of herein, including the Defendants' primary participation in the wrongful acts detailed herein occurred in this District; and (d) Defendants have received substantial compensation in this District by doing business here and engaging in numerous activities that had an effect in this District. JNJ's principal place of business is located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

PARTIES

9. Plaintiff Walter E. Ryan, Jr. brings this action derivatively in the right and for the benefit of the Company to redress injuries suffered by the Company as a direct result of the Defendants' breaches of fiduciary duty alleged herein. Plaintiff will adequately and fairly represent the interests of JNJ in enforcing and prosecuting its rights. Plaintiff is and was a citizen of Nevada and a continuous owner of stock of JNJ throughout all relevant times. Specifically, Plaintiff has been a shareholder since at least 2000 and currently owns at least 20,000 shares of JNJ common stock.

10. Nominal Defendant JNJ, a New Jersey corporation, engages in the research and development, manufacture, and sale of various products in the health care field worldwide. JNJ operates in three segments: Consumer, Pharmaceutical, and Medical Devices and Diagnostics.

11. Defendant William C. Weldon ("Weldon") is the Chief Executive Officer ("CEO") and Chairman of the Company's Board of Directors (the "Board"). Upon information and belief, Weldon is a citizen of Pennsylvania.

12. Defendant Mary Sue Coleman ("Coleman") is a member of the Board and is President of the University of Michigan. Upon information and belief, Weldon is a citizen of Michigan.

13. Defendant James G. Cullen ("Cullen") is a member of the Board and Retired President and Chief Operating Officer of Bell Atlantic Corporation. Upon information and belief, Cullen is a citizen of Virginia or New Jersey.

14. Defendant Michael M.E. Johns ("Johns") is a member of the Board and Chancellor of Emory University. Upon information and belief, Johns is a citizen of Georgia.

15. Defendant Susan L. Lindquist ("Lindquist") is a member of the Board. Upon information and belief, Lindquist is a citizen of Massachusetts.

16. Defendant Anne M. Mulcahy ("Mulcahy") is a member of the Board and Former CEO of Xerox Corporation. Upon information and belief, Mulcahy is a citizen of Connecticut or New York.

17. Defendant Leo F. Mullin ("Mullin") is a member of the Board and Retired CEO of Delta Air Lines, Inc. Upon information and belief, Mullin is a citizen of Georgia.

18. Defendant William D. Perez ("Perez") is a member of the Board and Senior Advisor of Greenhill Co. Upon information and belief, Perez is a citizen of Oregon.

19. Defendant Charles Prince ("Prince") is a member of the Board and Former CEO of Citigroup. Upon information and belief, Prince is a citizen of New York or Florida.

20. Defendant David Satcher ("Satcher") is a member of the Board. Upon information and belief, Satcher is a citizen of Georgia.

21. Unless otherwise noted, the Defendants named in paragraphs 11 through 20 are collectively referred to herein as the "Individual Defendants."

INDIVIDUAL DEFENDANTS' FIDUCIARY DUTIES

22. Individual Defendants are officers and directors of JNJ and therefore control the business and corporate affairs of JNJ. These Defendants owe JNJ and its shareholders fiduciary obligations of trust, loyalty, good faith and due care, and are required to use their utmost ability to control and manage the Company in a fair, just, honest and equitable manner. Individual Defendants, at all times, were required to act in the best interest of JNJ and its shareholders, without regard to their own self-interest.

23. By virtue of their positions as directors of JNJ, the Individual Defendants had at all relevant times, the power to and did control, influence and cause JNJ to engage in any wrongful acts and to omit material information alleged herein.

24. Each Individual Defendant is sued individually as a conspirator in his or her capacity as an officer and/or director of JNJ, and the liability of each arises from the fact that each engaged in actions that breached his or her fiduciary duties complained of herein.

25. Each Individual Defendant had an affirmative fiduciary obligation to act in good faith, truthfully, and in the best interests of JNJ and its shareholders. To diligently comply with these duties, the Individual Defendants were obligated to refrain from, or prevent, any action that:

(a) advanced or protected the interest of themselves or their colleagues at the expense of, or to the detriment of, the shareholders;

(b) wasted corporate assets; and

(c) allowed JNJ to disseminate material misleading or incomplete information.

26. In accordance with their duties of care, loyalty, good faith and candor, the Individual Defendants were obligated to disclose all material facts to shareholders.

27. By reason of their positions as directors and/or fiduciaries of JNJ and because of their ability to control the business and corporate affairs of the Company, the Individual Defendants owed and owe JNJ and its shareholders fiduciary obligations of loyalty, trust, candor and good faith and fair dealing. New Jersey law mandates that the Individual Defendants were and are required to act in furtherance of the best interests of JNJ and its shareholders.

SUBSTANTIVE ALLEGATIONS

28. From at least 1997 until the present, JNJ engaged in numerous illegal off-label marketing schemes that has brought scrutiny from federal regulators and private whistleblowers alike. In addition, JNJ subjected itself to a major product recall by ignoring previous U.S. Food and Drug Administration ("FDA") reports of malfeasance by one of its factories.

29. The Individual Defendants' inexcusable refusal to halt these practices has and will cost JNJ tens, if not hundreds, of millions of dollars in civil penalties, private litigation damages, and attorneys' fees.

30. Worse yet, the Individual Defendants hid many of these schemes, and the concomitant lack of adequate internal controls, from shareholders by omitting material information from JNJ's 2008 and 2009 filings with the U.S. Securities Exchange Commission ("SEC"), including the Company's annual proxy statements.

31. Detailed below are the specific schemes whereby JNJ and its wholly-owned subsidiaries illegally and sometimes dangerously, ran afoul of federal law.

1. **<u>JNJ's Deal with Omnicare to "Push" Certain Drugs</u>**

32. In August 1997 and again in 2004, Omnicare and JNJ agreed to an agreement whereby Omnicare would push JNJ products in return for tens of millions of dollars paid to Omnicare.

33. Specifically, Omnicare pharmacists recommended Risperdal (an anti-psychotic drug) for nursing home patients with Alzheimer's and dementia. Indeed, part of Omnicare's sales plan was to push Risperdal by:

a. Sending newsletters detailing Risperdal's use for "Dementia in the Elderly."

b. Targeting "key prescribers on a monthly basis using 'Target MD List.'"

c. Implementing an "Ask the Experts" forum for pharmacists.

34. This arrangement was illegal and, accordingly JNJ was sued by the federal government under, *inter alia*, the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b). JNJ knew that paying any kind of consideration in exchange for a company's recommending drugs was illegal. January 15, 2010 Complaint, *United States ex rel. Lisitza and Kammerer v. Johnson & Johnson, et al.*, 07-10288-RGS (D. Mass.) [docket no. 81] ("Fed. Compl."), ¶23.

35. In its Complaint, the federal government alleges that the Company paid kickbacks to Omnicare to induce it into purchasing and recommending JNJ's drugs. According to the Complaint, JNJ understood that Omnicare's pharmacists reviewed nursing home patients' charts at least monthly and made recommendations to physicians on what drugs should be prescribed for those patients and further alleges that JNJ knew that physicians accepted the Omnicare pharmacists' recommendations more than 80 percent of the time. Fed. Compl. at ¶21.

36. The federal government also alleges that JNJ paid kickbacks to Omnicare in numerous ways to induce Omnicare to push its drugs, including 1) that JNJ entered into agreements with Omnicare by which Omnicare was entitled to increasing levels of rebates from JNJ if Omnicare implemented specific programs to increase JNJ prescriptions, 2) that JNJ paid Omnicare millions of dollars for "data," much of which Omnicare never provided (the true purpose of these payments was to induce Omnicare to recommend JNJ drugs), 3) that JNJ made various other substantial bogus kickback payments to Omnicare, mislabeling the payments as "grants" and "educational funding." Fed. Compl. at ¶24.

37. The federal government further alleges that JNJ and its employees understood that it was a violation of the anti-kickback statute to offer or to pay remuneration, by whatever means, to induce a customer like Omnicare to purchase or to recommend JNJ's drugs. Fed. Compl. at ¶23.

38. As these allegations show, JNJ understood, yet repeatedly violated, the anti-kickback statute by paying Omnicare rebates to switch patients to JNJ's drugs, making payments to Omnicare for data (that JNJ was not actually receiving) as a substitute for rebates or discounts, and paying Omnicare various grants and sponsorship fees whose purpose was to induce Omnicare to purchase and to recommend JNJ drugs. According to the Complaint, JNJ recognized the problematical nature of its relationship with Omnicare. As one JNJ employee described a September 2002 internal meeting, JNJ's Omnicare sales team "got hammered re Healthcare Compliance." Fed. Compl. at ¶24.

A. JNJ's Kickbacks to Omnicare
Rebate Payments Contingent on Active Intervention by Omnicare

39. According to the Complaint, the drug supply agreement in place between JNJ and Omnicare in 1999 was signed on April 8, 1997, and had an ostensible term of April 1, 1997, to March 31, 2000 (hereinafter, the "1997 Agreement").

40. The 1997 Agreement provided for JNJ to sell Omnicare certain drugs, including Risperdal, Propulsid, Levaquin, Procrit, Duragesic, and Ultram, and for JNJ then to pay Omnicare quarterly market share rebates, where the percentage amount of the rebate on each drug increased as market share of that drug increased, and market share was determined based on Omnicare's purchases of each drug in comparison to Omnicare's purchases of competing products. The 1997 Agreement further required JNJ to pay Omnicare an "Annual Strategic Product Performance Rebate" on specific drugs that had "an Active Intervention Program (AIP) or Appropriate Use Program (AUP) applied in their favor." The 1997 Agreement defined AIP and AUP as follows:

> "**Active Intervention Program**" shall mean a program, applied by [Omnicare] and accepted by [JNJ] in writing, which is designed to appropriately shift market share to [JNJ]'s Product. Active interventions can include, but are not limited to, disease management disease management initiatives, written correspondence to Participating Providers prescribing or dispensing pharmaceutical products, educating nursing home staff regarding [JNJ]'s Products, [and] conducting clinical intervention programs through which consultant pharmacists recommend Supplier's Products when appropriate.
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> "**Appropriate Utilization Program**" or "AUP" shall mean a program applied by [Omnicare], and accepted in writing by Supplier, designed to cause the appropriate use of [JNJ]'s Products.

Fed. Compl. at ¶25.

41. In November 1998, JNJ and Omnicare signed an amendment to the 1997 Agreement concerning Levaquin. The amendment specified that:

> All Rebates are contingent upon the existence of and adherence to the following interventions:
>
> - Levaquin® will have a Selected formulary position and will be first line therapy for quinolones, when clinically appropriate and indicated. For the purpose of this Amendment, "Selected" shall mean ... Levaquin® is favored, when clinically appropriate and indicated, over all other branded drugs also available.
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> * * *
>
> - [Omnicare's] appropriate personnel will actively participate in educational and promotional programs discussing Levaquin®'s clinical advantages.

Fed. Compl. at ¶26.

42. In JNJ's words, JNJ intended all of its rebates to Omnicare to be "incentives to Omnicare to advocate appropriate use of JNJ products." JNJ calculated its return from the rebates it provided to Omnicare would ultimately provide $4.8 million in gains. Fed. Compl. at ¶27.

43. Another JNJ manager calculated that JNJ could generate the same return with just $1.44 million in rebate and that rebates were over 60% of Omnicare's net income model. Fed. Compl. at ¶27.

44. Indeed, the 1997 Agreement details that "a rebate shall be paid on each Product . . . according to and if . . . performance criteria are met quarterly."

45. The Board improperly allowed and or approved this illegal marketing scheme.

2. **JNJ's Off-Label Marketing of Topamax, Risperdal, Natrecor, and Bilinary Stents**

46. Beyond the deal to push its drugs through Omnicare, JNJ engaged in a campaign to market Topamax, Risperdal, Natrecor and Bilinary stents off-label through various subsidiaries. Despite clear "red flags" that each of these drugs were, or were suspected of being marketed off-label, the Individual Defendants consciously ignored red-flags and did nothing to stop or curb off-label marketing practices.

A. Topamax Off-Label Marketing Scheme

47. JNJ's 2003 annual report, filed with the SEC on Form 10-K (the "2003 10-K") disclosed that JNJ was under investigation for its off-label Topamax promotion. This filing put the Board on notice of JNJ's off-label marketing practices.

48. Defendants Weldon, Coleman, Cullen, Lindquist, Mullin, and Satcher signed the 2003 10-K, showing that they knew of government investigation into Topamax marketing. Ostensibly, the Board did nothing about this investigation and failed to prevent the alleged wrongdoing from occurring again.

49. JNJ received another subpoena in 2007 for Topamax showing that the Individual Defendants did nothing to stop Topamax's off-label promotion.

50. Specifically, the FDA approved Topamax as a migraine drug in 2004.

51. Despite the FDA's limited approval, JNJ caused its subsidiaries to promote it, and it was prescribed for:

a. bipolar disorder
b. counteracting weight-gain
c. alcoholism
d. obesity
e. binge eating
f. posttraumatic stress disorder

g. periventricular leukomaliacia
h. tremors
i. bulimia nervosa
j. smoking

52. Indeed, reports indicate that over 75% of all prescriptions for Topamax were off-label.

53. According to the federal government, it was the practice of JNJ's wholly-owned subsidiary, Ortho-McNeil Pharmaceutical, Inc. ("Ortho-McNeil"), to stage "Consultants Conferences" to disseminate claims about Topamax's off-label uses. Although the Consultants Conferences were purportedly comprised of local thought leaders for the purpose of providing independent advice on Topamax, in fact, they were little more than kickback-induced Ortho-McNeil promotional events. December 7, 2007 Second Amended Complaint, *United States ex rel. Spivack v. Johnson & Johnson, et al.*, 04-CV-11886 (MLW) (D. Mass.) ("Fed. Topamax Compl.") at ¶57.

54. Indeed, physicians invited to the Consultant Conferences were not asked for advice or expert consultation. Instead, Ortho-McNeil invited and paid physicians and other prescribers to attend a full-day "conference" that consisted of multiple presentations on Topamax's off-label uses. The Consultants Conferences were intended to influence participants' prescribing practices. Fed. Topamax Compl. at ¶58.

55. Ortho-McNeil held dozens, if not hundreds, of these Consultants Conferences across the country. Indeed, Ortho-McNeil presented Consultants Conferences on the off-label uses of Topamax in the areas of, *inter alia*, Psychiatry, Primary Care, Alcohol Dependence and Metabolic Syndromes. Fed. Topamax Compl. at ¶59.

56. Ortho-McNeil offered physicians an opportunity to attend the Consultants

Conferences by, *inter alia*, mailing unsolicited invitations directly to them. The invitations offered prescribing physicians an "honorarium" of $500 (if not more in certain instances), and reimbursement for mileage, tolls, parking, as well as accommodations at a four-star hotel and meals. Fed. Topamax Compl. at ¶60.

57. Those physicians who accepted the invitation were mailed a "Healthcare Provider Consulting Agreement" (the "Agreement") and directed to sign and return it to Ortho-McNeil in order to be paid the honorarium. The Agreement was created by Ortho-McNeil and presented to conference participants for their signature without discussion or negotiation. The Agreement's description of the "consultants" role is vague and undefined; for example, with respect to the "Psychiatry Consultants" role, the Agreement states only that consultants shall "observe and evaluate" data that "will address various affective and psychiatric issues including mood and anxiety disorders, alcohol dependence, eating disorders, weight-management issues, [and the] clinical development of Topamax." Fed. Topamax Compl. at ¶61.

58. In fact, the Conferences were intended not to solicit participant expertise and insight, but rather to aggressively promote Topamax's off-label uses and to influence the attendees' prescribing behavior. At an October 11, 2003 Consultants Conference in Washington DC, for example, Ortho-McNeil and its agents repeatedly commented that Topamax has "a wide variety of uses," and that Ortho-McNeil wanted to make Topamax "available to a wider audience" and to provide participant-prescribers with "food for thought" and "evidence" so that prescribers will decide how they "want to use Topamax." Fed. Topamax Compl. at ¶62.

59. The Agreement is not a bona fide consulting arrangement. Rather, the federal government alleged it was a sham "contract" created to disguise the true nature of Ortho-McNeil's arrangement with prescribing providers - *i.e.*, to provide a substantial financial

inducement to encourage providers to attend company events that promote the off-label prescription of Topamax and thereby increase Ortho-McNeil sales. Fed. Topamax Compl. at ¶63.

60. Ortho-McNeil paid the provider-participants approximately $500 (and possibly more in some instances) simply to attend a single "Consultants Conference," which did not reflect the value of services provided because the participating provider was not required to do anything but show up to receive his or her payment. Although providers were asked to respond to multiple choice questions posed through an "automated response system," Ortho-McNeil's questions, for the most part, either reinforced the content of off-label presentations or provided market survey information for Ortho-McNeil. Each of these payments allegedly constituted a reward or kickback for the purpose of influencing the recipients' prescribing practices. Fed. Topamax Compl. at ¶65.

61. Indeed, although the generic version of Topamax was not yet available, the likelihood of generic competition in the near future allegedly created strong financial incentives for Ortho-McNeil to encourage and promote Topamax's off-label uses in the immediate term. Fed. Topamax Compl. at ¶67.

62. Conference participants are exposed to a full-day of presentations on Topamax's unapproved uses, as speakers at Ortho-McNeil's conferences loaded their presentations with off-label representations and claims. For example, it was alleged that Dr. Alan Blau (Neuroscience Scientific Liaison for Ortho-McNeil) represented that Topamax's evolving spectrum of clinical use that included use in treating, *inter alia*, essential tremor, diabetic neuropathic pain, mood disorders, alcohol dependence, eating disorders, post-traumatic stress disorder, Tourette's

syndrome, obsessive compulsive disorder, obesity and Type 2 diabetes. Fed. Topamax Compl. at ¶68.

63. These uses were unapproved by the FDA, and Ortho-McNeil's wide-ranging claims were alleged to be often misleading and lacking adequate scientific and clinical support. Fed. Topamax Compl. at ¶69.

64. Other Consultant Conference speaker presentations were allegedly similarly permeated with impermissible off-label treatment claims. In particular, Ortho-McNeil emphasized Topamax's off-label use in (1) weight loss and control, (2) alcohol dependence (and other addictions and "cravings"), and (3) eating disorders such as binge-eating/bulimia. Fed. Topamax Compl. at ¶71.

65. These claims also were allegedly misleading and lacking scientific and clinical support. Fed. Topamax Compl. at ¶¶72-76.

66. The federal government further asserted that, under the Food and Drug laws, drug manufacturers were prohibited from making exaggerated, unsupported or misleading claims as to the efficacy of their drugs, but Ortho-McNeil disregarded this prohibition by, among other things, improperly claiming that Topamax was at least as good as, if not superior to, Prozac in treating eating disorders, or that Topamax's weight loss effects were comparable to Fen-Phen. The federal government alleged that, without head-to-head clinical studies of Prozac and Topamax, or Topamax and Fen-Phen, Ortho-McNeil had no scientific basis for these claims. Fed. Topamax Compl. at ¶77.

67. In virtually all cases, the federal government alleged that the "off-label" studies referenced or presented by Consultant Conference speakers to support their off-label claims were

funded by Ortho-McNeil or a related JNJ entity and were based on small patient populations. Fed. Topamax Compl. at ¶78.

68. The federal government sued JNJ because of the Topamax off-label marketing practices, and JNJ resolved the case by agreeing to plead guilty to a misdemeanor and pay a $6.14 million criminal fine for the misbranding of Topamax in violation of the Food, Drug and Cosmetic Act.

69. In addition to the criminal fine, JNJ agreed to pay $75.37 million to resolve civil allegations under the False Claims Act that they illegally promoted Topamax and caused false claims to be submitted to government health care programs for a variety of psychiatric uses that were not medically accepted indications and therefore not covered by those programs.

70. If the Individual Defendants had not consciously ignored the numerous red-flags or implemented adequate internal controls, JNJ would not have been subject to the massive penalities.

B. Risperdal Off-Label Marketing Scheme

70. JNJ's 2003 10-K also disclosed that the Company had received a subpoena from the federal government in connection with its off-label Risperdal marketing scheme. JNJ was also sued by several States' attorneys general for dangerously marketing Risperdal off-label.

71. For instance, in the State of Texas' complaint against JNJ, and several of its wholly-owned subsidiaries, including Janssen, L.P., Texas alleged that beginning in the early 1990s and through the date of filing, drug companies developed new schizophrenia drugs known as atypical antipsychotics ("atypicals"). The cost of these atypical anti psychotics far exceeded the cost of the older generation of antipsychotic drugs which had been available in generic form for decades. The older generation antipsychotic drugs first appeared in the 1960s, and were

known as typical antipsychotics ("typicals") or conventional or first generation anti psychotics, or traditional neuroleptics. December 12, 2008 Second Amended Petition, *State of Texas ex rel. Jones v. Janssen, L.P., et al.*, Cause No. D-1GV-04-001288 (Travis County District Court) ("Tex. Compl.") at ¶ 6.1.

72. On December 29, 1993, Risperdal received FDA approval, and in January 1994, Texas alleged that JNJ launched the atypical antipsychotic, Risperdal, entering a market which was dominated at the time by Clozaril. At that time, Risperdal was approved for use only in adults for the management of the manifestations of psychotic disorders. In 2000, the FDA revised the language to be used in manufacturer labeling to describe the approved use for atypical antipsychotics from "the management of the manifestations of psychotic disorders" to "treatment of schizophrenia." In early 2002, JNJ's subsidiary, Janssen, complied with the FDA requirement by revising the Risperdal label to clarify that its FDA approval was for use in schizophrenic adults only and in October 2003, launched a long-acting injectable form of Risperdal, which received the same limited FDA approval for use in schizophrenic adults. In December 2003, the FDA approved Risperdal for short term treatment of adults with Bipolar I disorder. Thus, Texas alleged that from the product launch in 1994 until late 2006, Risperdal had no FDA-approved indication for any use in the child and adolescent population. In October 2006, Risperdal received a narrow indication for use in the limited population of children and adolescents (age 5-17) for irritability associated with a diagnosis of autism. Additional narrow indications for Risperdal were approved by the FDA in August 2007 for Schizophrenia in adolescents (age 13-17) and for manic or mixed episodes of Bipolar I in children and adolescents (age 10-17). Tex. Compl. at ¶ 6.2.

73. Texas further alleged that Risperdal was a drug for use in the treatment of schizophrenia, but schizophrenia's occurrence in the United States population ranges from 0.55% to 1 %, which was a tiny market compared to what JNJ needed to make Risperdal a blockbuster drug. Knowing this limitation on the market, JNJ allegedly engaged in a sophisticated marketing plan to establish Risperdal as a preferred drug with a broad use position well beyond its FDA approved indication. Tex. Compl. at ¶ 6.3.

74. Under the guise of medical education, scientific research and patient advocacy literature, JNJ allegedly targeted public sector payors in States with substantial populations of Medicaid patients with mental illness by promoting Risperdal as appropriate for a broad range of mental illnesses, symptoms and disorders, and further allegedly targeted state and federal government public health systems with their marketing plan designed to promote Risperdal. In doing so, Texas alleged that JNJ misrepresented the safety, superiority, appropriate use, efficacy, and cost effectiveness of Risperdal to, at least, that State's Medicaid prescribers and decision-makers. Tex. Compl. at ¶ 9.1.

75. Texas also alleged that JNJ used sophisticated strategies and tactics to disseminate misrepresentations about Risperdal to Texas Medicaid prescribers and decision-makers about Risperdal's safety, superiority appropriate use efficacy and cost effectiveness. These strategies included control over speeches and publications by individuals deemed by JNJ to be "key opinion leaders" and advocacy group messages, engaging in such tactics to "seed the literature" and increase the "noise level" in the public and healthcare communities about Risperdal. JNJ also allegedly compromised the objectivity of researchers, prescribers and public mental health decision-makers by deeming them to be "key opinion leaders," "advisors," and "experts" and

providing inducements including research funding, consulting fees, extravagant meals and travel accommodations, honoraria and enhanced professional reputation. Tex. Compl. at ¶ 9.2.

76. Texas further asserted that JNJ masked its undue influence and fraudulent scheme by using third party vendors and advocacy organizations as a conduit to funnel their funding and control. Texas pointed to additional marketing tools employed by JNJ, such as publications and presentations targeting medical professionals and state mental health decision makers, which were disseminated by third-party contractors, giving the impression that the information received was from an independent source. Texas alleged that JNJ deployed and funded advocacy groups to influence legislation and state policy for the benefit of Risperdal. Texas asserted that JNJ's claims that Risperdal was a broad-use, safer, more cost-effective and efficacious medication which the mental health community should choose, not only over cheaper typical generic medications, but also over other available atypical, was central to all these marketing vehicles. Tex. Compl. at ¶ 9.4

77. Once again, the Individual Defendants approved and/or ignored the acts that led to significant exposure for JNJ's off-label marketing.

C. Natrecor Off-Label Marketing Scheme

78. Natrecor was developed by Scios Inc. ("Scios") and was approved by the FDA in 2001 for a limited purpose, specifically patients with congestive heart failure who have dyspnea at rest. JNJ bought Scios in 2003 for $2.5 billion.

79. At the time of the transaction, Scios was engaged in aggressive off-label marketing schemes. JNJ knew about these marketing schemes and acknowledged its intent to continue promoting Natrecor off-label as a "unique product for a largely underserved and growing market."

80. JNJ's first disclosure of the government investigation into Natrecor was in August 2005, in the Company's quarterly report for the period ended July 3, 2005, filed with the SEC on Form 10-Q, where it was disclosed that JNJ received a subpoena. In the Company's annual report for 2008, filed with the SEC on Form 10-K (the "2008 10-K"), JNJ disclosed a criminal investigation into the marketing practices for Natrecor, but did not disclose that three *qui tam* complaints had been filed against JNJ in connection with that product.

81. Although JNJ eventually disclosed the *qui tam* cases, these cases show the pervasive off-label marketing JNJ conspired to commit. Specifically, as alleged in one of the complaints in these actions:

> Since the inception of Relator's employment at SCIOS, the upper management has always permitted and encouraged active off-label marketing. Off label sales were tied to Sales Representatives' incentive quotas and sales goals.
>
> DEFENDANTS utilized kickbacks to encourage sales of Natrecor. The kickback schemes were varied, and include but were not limited to, marketing the spread, offering kickbacks to physicians in the form of phony drug trials, "stipends" to register patients in the ADHERE Registry; lavish entertainment and gift giving, phony speaker fees, honorariums, travel funds, phony grants, phony preceptorships, "investigator" meetings, a/k/a "speaker" meetings, a/k/a "advisory board" meetings, a/k/a "consultant" meetings. and providing incentives to set up infusion clinics.
>
> Offering Kickbacks to Physicians in the Form of Clinical Phony Drug Trials and/or "Investigator (Physician) Initiated" Trials/Studies
>
> Up to in or about December, 2004, DEFENDANTS set up supposed clinical trials and/or "investigator initiated" trials/studies for off-label uses of Natrecor, solely for the purpose of generating sales. Unlike legitimate clinical trials or studies: (1) Most clinical trials and/or "investigator initiated" trials/studies were partially managed by the DEFENDANTS' sales force, not its research division; (2) The sales force typically had knowledge of all aspects the trials and/or "investigator initiated" trials/studies and regularly made joint calls with the DEFENDANTS' Scientific Affairs Managers ("SAMs") to physicians (3) The sales force lobbied to have the maximum number of trials and/or "investigator initiated" trials/studies in their territories due to the fact that clinical trials and/or "investigator initiated" trials/studies generate prescriptions, which helped Sales Representatives attain sales goals; (4) The sales force regularly consulted with the SAMs to check on the status of the trials and/or studies patient accrual (which

correlates with future additional sales); (5) SAMs have outwardly admitted that their primary role is to drive sales for the sales force., and support sales force in off-label marketing which included CT surgery, nephrology, continuous infusion and outpatient infusion as part of the business plan; (6) SAMs received a bonus system that rewarded them on company sales; (7) SAMs have taken credit for Sales Representatives' success in generating sales dollars.

DEFENDANTS provided remuneration for clinical trials and/or "investigator initiation"; studies/trials as a means to induce physicians to prescribe Natrecor. The "research" performed had no legitimate value to DEFENDANTS and were merely pretexts tor payments for prescriptions.

The clinical trials and/or "investigator initiated" studies/trials begin with the DEFENDANTS' Sales Representatives and/or SAMs negotiating with the physician how much the physician needs in compensation, per patient, trial, and/or "investigator initiated" studies/trials to conduct a clinical trial and/or an "investigator initiated" study/trial.

Thereafter, DEFENDANTS' SAM meets with the physician(s) and sets up the study. Typically, there were 25-200 patients in a study, and the duration was up to 12 months. The physician buys Natrecor from a distributor, such as those described previously and then bills Medicare for the physician visits and the Natrecor.

As a result of said trials, DEFENDANTS caused claims to be submitted by providers for Natrecor (as well as infusion claims, office visit claims and other claims for services), resulting in Government Program reimbursement to providers in the millions of dollars, in violation of the False Claims Act, 31 U.S.C. §3729 *et seq.* and the Anti-Kickback Act, 42 U.S.C. §1320a-7b(b)(2)(A).

December 1, 2005 First Amended False Claims Act Complaint, *United States ex rel. Strom v. Scios, Inc. And Johnson & Johnson*, No. C 05-3004-CRB (N.D. Cal.) ("Scios Compl."), ¶¶ 23-29.

82. The Individual Defendants knew of, or consciously disregarded, these practices because they were charged with approving Scios's purchase. The Individual Defendants had an obligation and opportunity to perform due diligence on Scios, but either ignored or approved Scios's "off-label" practices.

D. Bilinary Stents Off-Label Marketing Scheme

83. Similar to Topamax, Risperdal and Natrecor, JNJ allegedly engaged in a scheme to unlawfully market Biliary Stents off-label. A biliary stent is device implanted into the bile duct when a patient has terminal biliary cancer. A patient with biliary cancer experiences bile flow and drainage issues, which the stent helps to regulate.

84. A biliary stent is a temporary relief to a dying patient. In contrast, a vascular stent is a permanent and dangerous device that requires strict FDA approval. Because vascular stents are more stringently regulated, JNJ allegedly had the opportunity to market biliary stents to a larger market.

85. Under federal law, if biliary stents are used for purposes other than its FDA pre-market approval, it is considered "adulterated" and not covered by Medicare and/or Medicaid. JNJ allegedly marketed the biliary stents off-label for use as vascular stents to circumvent the more stringent vascular stent approval process.

86. JNJ, along with other medical device manufacturers, was sued in a federal *qui tam* action in connection with this off-label marketing scheme, in which JNJ allegedly promoted and marketed biliary stents off-label as vascular stents intended to treat peripheral vascular disease. The relator's allegations, based on his position as a territory sales manager for a competitor of JNJ, are powerful. For example, the complaint in that action alleges that JNJ, together with another of its subsidiaries, Cordis Corporation, and two other companies, engaged in the following wrongful conduct:

A. Defendants instructed sales representatives to target physicians specializing in peripheral vascular disease to induce the use of the Class IT biliary stents as unapproved Class III vascular stent intended for vascular disease.

B. Defendants directly or indirectly sponsored or funded studies of the offlabel

use of the biliary stents to treat peripheral vascular disease and provided the study information to sales representatives for use in marketing and promoting the devices to vascular physicians.

C. Defendants extensively marketed and promoted the devices in print and electronic advertisements targeting physicians with vascular specialization. The objective intent of the marketing was to solicit the use of the devices as intended for the vascular system. Essentially no print and electronic marketing of the biliary stents targeted gastroenterologists and hepatologists (physicians specializing in biliary tree disorders).

D. Defendants provided unsolicited marketing and promotional literature to physicians concerning the off-label use of the unapproved biliary stents to treat vascular disease. Among the unsolicited literature was information advising physicians how to develop and expand a peripheral vascular practice, thereby encouraging the unapproved use of the biliary stents.

E. Defendants prepared patient "advisory" letters and similar documents concerning the health risks of undiagnosed and untreated peripheral vascular disease. The documents were distributed to vascular specialists, without solicitation, to send to patients to generate patient interest in peripheral vascular disease and to induce the unapproved use of the biliary stents. The unsolicited documents warned patients of severe, life-threatening medical consequences associated with undiagnosed and untreated peripheral vascular disease such as "kidney damage or failure, tissue damage and, in extreme cases, amputation of affected extremities."

F. Sales representatives were given mandatory quotas requiring them to sell the biliary stents off-label simply to satisfy the quota. Sales representatives were compensated with bonuses for off-label sales.

G. Biliary stents were consigned to healthcare providers 10 promote usage. Stent inventory was allocated to hospital departments that do not perform biliary procedures, but do perform vascular stenting. Utilization rates were closely monitored by sales representatives .. The information was reported regularly to management for use in developing business plans and utilization rate projections based on the off-label use of the biliary stents.

H. Defendants provided reimbursement guidelines and manuals to physicians that instructed physicians to falsely code reimbursement claims using procedural codes for approved vascular stents, even though an unapproved biliary stent was utilized.

December 5, 2007 Second Amended Complaint under Federal and State False Claims Acts, *United States ex rel. Colquitt v. Abbott Laboratories, et al.*, No. 3-06-CV-1769-M (N.D. Tex.) ("N.D. Tex. Compl."), ¶9.

87. JNJ's alleged marketing and promotion of the unapproved biliary stents as Class III vascular stents intended for use in the vascular system without premarket approval of the FDA renders the biliary stents adulterated medical devices under 21 U.S.C. § 351(f) and makes them not covered by Medicare and Medicaid. N.D. Tex. Compl., ¶10.

C. JNJ's Product Recall

88. In 2010, Individual Defendants failed to disclose that JNJ would be issuing a product recall based on a FDA report that detailed major GMP and other issues with one of the production facilities at another JNJ subsidiary, McNeil-PPC, Inc. ("McNeil").

89. On May 4, 2010, the FDA released a report pertaining to an inspection of the facilities of McNeil in Fort Washington, Pennsylvania (the "FDA Report"). The FDA Report was issued by four local investigators from the FDA, and was issued to McNeil's Vice President of Operations. The FDA Report concerned inspections of McNeil which took place between April 19, 2010 and April 30, 2010.

90. According to the FDA Report, there were 20 separate "observations" made by the FDA investigators respecting deficiencies in the manufacturing operations at McNeil. These observations included the following:

> **Observation 1**: The responsibilities and procedures applicable to the Quality Control Unit are not fully followed. The Quality Control Unit Authorities (hereinafter "QA") most responsible for overseeing daily operations at McNeil did not insure that responsibilities for quality assurance were enforced. Such lapses in oversight, led to raw materials with "known contaminations" to be included in the manufacture of Children's and Infant's Tylenol drug products which are still on the market today.

Observation 2: There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Specifically, problems were found with the manufacture of Infant's Dye- Free Tylenol Suspension Drops, Cherry formula.

Observation 3: Control procedures fail to include adequacy of mixing to assure uniformity and homogeneity.

Observation 4: Control procedures are not established which monitor the output and value the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of inprocess material and the drug product. Specifically, the FDA Report observed that "control procedures used did not validate the manufacturing processes that cause variability in the characteristics of the drug product." The FDA Report cites the processing of "super potent batches" including batches for Infant's Dye-Free Tylenol Suspension Drops.

Observation 5: Written production and process control procedures are not followed in the execution of production and process control functions. Specifically, no Corrective Action Preventative Action ("CAPA") process was initiated for batches of Children's Drugs from May 2009 through April 2010 where "foreign material, particulate matter and/or contamination were observed." In addition, no CAPA was initiated for 46 consumer complaints that were made regarding "foreign materials, black or dark specks from June 2009 to April 2010."

Observation 6: There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed. Specifically, a thorough investigation or additional analytical testing was not conducted for Infant's Dye-Free Tylenol Suspension Drops, Cherry, 80 mg/0.8mL. Further, "vendor lots" from December 4, 2008 and December 23, 2008 were "contaminated with gram-negative organisms." These lots were used to manufacture the following Tylenol Infant and Children's products which were marketed/distributed and remained within expiration dating as follows:

(1) Tylenol Infant's Drops, 80 mg/0.8mL, expiration date 11/10
(2) Tylenol Oral Suspension, expiration date 11/10
(3) Tylenol Oral Suspension, expiration date 11/10
(4) Tylenol Oral Suspension, expiration date 11/10
(5) Children's Tylenol Plus Cold, expiration date 11/10
(6) Children's Tylenol Plus Multi-Symptom Cold, expiration date 11/10
(7) Children's Tylenol Plus Cold, expiration date 11/10
(8) Children's Tylenol Plus Multi-Symptom Cold, expiration date 12/10
(9) Children's Tylenol Oral Suspension, expiration date 11/10

(10) Children's Tylenol Oral Suspension, expiration date 11/10
(11) Children's Tylenol Plus Multi-Symptom Cold, expiration date 11/10
(12) Children's Tylenol Plus Cold & Cough, expiration date 12/10
(13) Infant's Tylenol Drops, expiration date 12/10
(14) Children's Tylenol Oral Suspension, expiration date 12/10
(15) Infant's Tylenol Drops, expiration date 12/10
(16) Infant's Tylenol Drops, expiration date 12/10
(17) Children's Tylenol Oral Suspension, expiration date 11/10
(18) Children's Tylenol Plus Cold & Cough, expiration date 12/10
(19) Children's Tylenol Oral Suspension, expiration date 12/10
(20) Children's Tylenol Oral Suspension, expiration date 12/10
(21) Children's Tylenol Plus Cold and Cough, expiration date 12/10
(22) Children's Tylenol Oral Suspension, expiration date 12/10
(23) Children's Tylenol Oral Suspension, expiration date 12/10
(24) Children's Tylenol Oral Suspension, expiration date 12/10
(25) Tylenol Infant's Drops, expiration date 12/10
(26) Children's Tylenol Plus Cold & Cough, expiration date 12/10.

Observation 7: Training is not conducted with sufficient frequency to assure that employees remain familiar with current, good manufacturing practices requirements applicable to them.

Observation 8: Procedures describing the handling of all written and all complaints regarding a drug product are not followed. Specifically, a problem in this regard was noted with respect to Infant's Dye-Free Tylenol Suspension Drops, Cherry.

Observation 9: Each container dispensed to manufacturing is not examined by a second person to assure weight and measure are correct as stated in the batch records. Specifically, a problem in this regard was noted with respect to Infant's Dye-Free Tylenol Suspension Drops, Cherry.

Observation 10: Strict control is not exercised over labeling. Specifically, labeling was accessible to all warehouse operators and personnel and was not kept in a locked environment with limited access.

Observation 11: No written testing program designed to assess the stability of drug products. Specifically, there is a lack of stability data to support the expiration date assigned to lots produced following the manufacturing change for Infant's Dye-Free Tylenol Suspension Drops, Cherry.

Observation 12: Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that components and drug products confirm to appropriate standards of identity, strength, quality and purity. Specifically, it is unknown why the firm does not test

TSA, a non-selective general microbial growth medium, during growth promotion tests.

Observation 13: The quality control unit does not have access to adequate lab facilities for testing and approval or rejection of components and drug products. Specifically, the calibration, airflow and leakage were affected. Also, during the walkthrough of the Microbiological Laboratory, many deviations were observed regarding dust, debris and lack of cleanliness. Specific deviations were observed during microbiological testing of Children's Zyrtec Sugar Free Syrup.

Observation 14: Laboratory records do not include complete records of the periodic calibration of laboratory instruments, gauges, and recording devices. Specifically, laboratory refrigerators were not calibrated adequately.

Observation 15: Written specifications for laboratory controls do not include a description of the sampling procedures used. Specifically, it does not identify the dilution to use or the microbiological swab used for swabbing equipment after cleaning for Bioburden samples.

Observation 16: Samples taken of in-process materials for determination of conformance to specifications are not representative. Specifically, the raw material samples pulled by the manufacturer are not a representative sample.

Observation 17: Each lot of components was not appropriately identified as to its status in terms of being quarantined, approved or rejected. Specifically, there were not separate or defined areas to prevent contamination or mix-ups.

Observation 18: Components are not microscopically examined when appropriate. Specifically, there are no monthly trend reports.

Observation 19: Records are not kept for the maintenance and inspection of equipment.

Observation 20: The persons double-checking the cleaning and maintenance are not dating and signing or initialing the equipment cleaning and use log.

91. The FDA Report and the ensuing recall was not the first time that McNeil products have been cited by the FDA. In fact, according to the FDA's January 11, 2006 Enforcement Report (the "Enforcement Report"), many of the same Recalled Children's Drugs involved in the subject recall were cited by the FDA over four years ago for ***the same reasons*** that they were cited in the FDA Report.

A. Prior Reports by the FDA

92. Specifically, the Enforcement Report details that Children's Motrin Bubblegum Suspension 4 oz. bottle, one of the Recalled Children's Drugs, was the subject of FDA Recall # D-081-6, stating that McNeil was notified about the recall by letter dated September 19, 2005, and that the recall was necessary because of the "presence of particulate matter" in the product. As detailed above, the presence of particulate matter in this Recalled Children's Drug is the subject of Observation No.5 in the FDA Report.

93. Similarly, the Enforcement Report details two other Recalled Children's Drugs that were the subject of citations and recalls for the "presence of foreign substance": NDC # 50580- 407-04, Bubblegum Yum Flavor Children's Tylenol Oral Suspension 4 oz. bottles (which was the subject of Recall # D-090-6) and NDC # 50580-123-04, Cherry Blast Flavor Children's Tylenol Oral Suspension 4 oz. bottles (which was the subject of Recall # D-091-6).

94. The Enforcement Report further states that NDC #50580-601-04, referring to Original Berry Flavor Children's Motrin Oral Suspension 4 oz. bottles, was the subject of Recall # D-088-6. That Recalled Children's Drug was recalled previously in 2005 for being "subpotent." In contrast, many of the drugs identified in the FDA Report are being recalled for being "superpotent," meaning that the drugs contain too much of the active ingredient as opposed to too little.

4. Defendants Caused JNJ's 2008 and 2009 Proxy Statements to Be Inaccurate and Misleading

95. JNJ's Proxy Statements for 2008 and 2009, filed with the SEC and disseminated to the Company's shareholders on or about March 12, 2008 and March 11, 2009, respectively (the "Proxy Statements"), were materially misleading in that they omitted material facts. These

omissions caused harm to the Company in that, among other things, the numerous and blatant legal violations that occurred within the Company were kept hidden. The undisclosed illegal activity resulted in various *qui tam* actions, as alleged herein, in which some the federal government intervened and took control of the prosecution, and others are being prosecuted by States' attorneys general. The Individual Defendants also withheld that JNJ's internal controls were not effective in preventing, among other things, the recent massive product recall.

96. The Proxy Statements were disseminated to the Company's shareholders in order to solicit and gather their approval of important and legally required matters and to obtain their consent and votes for the election of the Individual Defendants, in each case upon the Board's explicit recommendation as to which Individual Defendants should be elected.

97. Under each director's general fiduciary duties imposed under New Jersey law, the specific duties applicable of directors set forth in JNJ's foundational corporate documents, and by the federal securities laws, the Board is mandated to fully disclose all information material to shareholders' decision concerning how to cast their votes in connection with the election of Board members in 2008 and 2009.

98. Collectively ignoring its fiduciary duties, the Board caused JNJ to file and disseminate the materially inaccurate Proxy Statements. Specifically, in the Proxy Statements, the Individual Defendants provided materially similar information and disclosures concerning the Company, the general responsibilities of the Board and its committees, and the basis upon which the members of the Board (or prospective members of the Board) were seeking election to another (or initial) term of office. In addition, JNJ mailed the Proxy Statements to shareholders concurrently with the mailing of the Company's annual report.

99. The Individual Defendants failed to disclose material information to shareholders concerning critical aspects of the Board's responsibilities and activities, such as the Board's obligation to assure compliance with applicable drug laws and regulations, and the fact that the financial and operating metrics disclosed in the Proxy Statements were the result of widespread criminal misconduct within JNJ that the Board was duty-bound to prevent.

100. The Proxy Statements were also materially inaccurate and incomplete, because they did not disclose that JNJ reaped hundreds of millions of dollars from Omnicare as a result of illegal kickbacks, that JNJ violated federal law, and that JNJ faced hundreds of millions in exposure from civil actions.

101. If shareholders had been provided with complete and accurate information concerning the Board's failure to perform its duties -- including with respect to presiding over JNJ's extensive violations of applicable laws – the Board would not have been elected (or reelected).

102. The Individual Defendants' election inflicted significant harm on JNJ. Basically, the Board's failure to actually perform the affirmative legal and compliance obligations directly caused and perpetuated JNJ's continued violation of the drug laws and regulations as alleged herein. For example, instead of settling with the federal government as Omnicare did, the Board has directed JNJ defend against the charges, exposing JNJ to treble damages and the possibility of no longer being able to participate in Medicaid or Medicare.

103. The Board's assumed compliance duties under applicable laws was directly relied upon by others – including federal regulators and JNJ's shareholders -- who, based on that reliance, refrained from taking action to terminate JNJ's systematic legal violations. This reliance on the Board's assumption of duty caused direct detriment to the Company, which, in the

absence of the Board's fulfillment of its obligations, was left helpless to prevent the misconduct occurring in its name.

DAMAGES TO THE COMPANY

104. The Individual Defendants breached their fiduciary duties to JNJ in connection with JNJ's multiple illegal marketing schemes as alleged herein, and exposed the Company to a wide variety of financial harm including:

(a) government fines and civil liabilities;

(b) rebates to consumers;

(c) loss of financial goodwill;

(d) damages and legal defense costs for consumer fraud and *qui tam* litigations;

(e) costs related to compensation, severance and benefits paid to the defendants who have breached their fiduciary duties to JNJ; and

(f) substantial additional future costs to remediate its failed corporate governance processes and institutional operations.

DERIVATIVE AND DEMAND FUTILITY ALLEGATIONS

105. The current Board consists of the following ten Defendants: Weldon, Coleman, Cullen, Johns, Lindquist, Mulcahy, Mullin, Perez, Prince and Satcher. Plaintiff has not made any demand on the present Board to institute this action because such a demand would be a futile, wasteful and useless act, particularly for the following reasons:

The Board has Breached Its Fiduciary Duties, Faces a Substantial Likelihood of Significant Liability and Cannot Exercise Independent Judgment To Prosecute Litigation Against Themselves

106. The Board consists of the ten Individual Defendants named herein. To bring this suit, all of the Individual Defendants would be forced to sue themselves and persons with whom they have extensive business and personal relationships, which they will not do, thereby excusing demand. Indeed, the entire Board is antagonistic to this lawsuit. As an example, the Board has shown a combative posture in responding to congressional inquiries[2] and even mere requests for corporate records have been rejected, indicating the Board's unwillingness to address the serious problems posed by the Company's repeated alleged wrongdoing.

107. As more fully detailed herein, the Individual Defendants participated in, approved and/or permitted the wrongs alleged to occur and participated in efforts to conceal or disguise those wrongs from JNJ's shareholders, or recklessly and/or negligently disregarded the wrongs complained of, and are therefore not disinterested parties, as each faces a substantial likelihood of liability for his or her conduct as alleged herein.

108. By virtue of their specific duties as Board members, each of the Individual Defendants was charged with the management of JNJ and to conduct the Company's business affairs. Each of the Individual Defendants breached the fiduciary duties that they owed to JNJ and its shareholders because they caused or failed to prevent and correct the internal control deficiencies, improper statements and wrongful conduct.

109. The Individual Defendants cannot exercise independent objective judgment in deciding whether to bring this action or whether to vigorously prosecute this action because the

[2] NATASHA SINGER, *Drug Maker Seen as Uncooperative on Inquiry*, New York Times, http://www.nytimes.com/2010/06/11/health/11drug.html?scp=2&sq=johnson%20&%20johnson&st=cse (last visited June 15, 2010).

Board members are interested personally in the outcome, as their actions or failures to act have subjected JNJ to potentially hundreds of millions of dollars in total liability for violations of applicable drug laws and regulations, applicable securities laws, engaging in possible consumer fraud, and damaging JNJ's goodwill.

110. In the event that Individual Defendants were to bring this derivative action against themselves, they would be forced to expose their own misconduct, which also underlies allegations in the consumer fraud and *qui tam* litigations. The potential total liability arising from such civil litigation and criminal investigations is likely to exceed the limits of insurance coverage available to the Individual Defendants, thus exposing them to personal liability. For these reasons, the Board Member Defendants cannot exercise the independent judgment necessary to prosecute the claims alleged herein since it would require them to take positions contrary to their own defenses in the pending litigations.

111. Indeed, as a result of the wrongdoings complained of, JNJ has and will continue to be exposed to substantial losses. But the Individual Defendants have not filed any lawsuits against themselves or others who were responsible for wrongdoing.

112. The Individual Defendants also face a substantial likelihood of liability for misstatements contained in JNJ's 2008 and 2009 proxy statements.

113. All the Individual Defendants, except Defendant Mulcahy, disseminated the proxy statements that omitted material information regarding JNJ's business practices.

Individual Defendants' Committee Assignments Also Show a Substantial Likelihood of Liability for the Majority of Directors

114. Defendants Lindquist, Mullin, Perez and Satcher served as members of the Board's Public Policy Committee.

115. According to JNJ's website, the Public Policy Committee "[r]eviews JNJ's governmental affairs and policies and other public policy issues facing the Company" and "[a]dvises and makes recommendations to the Board on these issues as appropriate."

116. Because they had the ability to review internal corporate documents, request documents for review, communicate directly with other senior managers of the Company, corporate officers and employees and attend management and Board meetings, each of the Individual Defendants either knew about the matters alleged herein and failed to take appropriate action, or failed to obtain adequate information about the matters alleged herein so they could remain properly informed about JNJ's practices, policies, controls and business operations.

117. Defendants Coleman, Cullen, and Mullin served as members of JNJ's Audit Committee.

118. The Audit Committee: 1) helps oversee JNJ's accounting and reporting practices; 2) recommends independent public accountants for appointment by the Board and reviews their performance; 3) monitors adequacy of internal accounting practices, procedures and controls; and 4) reviews all significant changes in accounting policies.

119. Defendants Coleman, Cullen, and Mullin had the ability to review internal corporate documents, request documents for review, communicate directly with other senior Company managers, corporate officers and employees and attend management and Board meetings, each of the Individual Defendants either knew about the matters alleged herein and failed to take appropriate action, or failed to obtain adequate information about the matters alleged herein so they could remain properly informed about JNJ's practices, policies, controls and business operations, and further failed to disclose material information in the Proxy Statements.

120. Therefore, Defendants Lindquist, Mullin, Perez , Satcher, Coleman and Cullen face a sufficiently substantial likelihood of liability for their breach of fiduciary duties and demand upon them is futile. The Individual Defendants, as more fully detailed herein, participated in, approved and/or permitted the wrongs alleged herein to occur and participated in efforts to conceal or disguise those wrongs from JNJ's stockholders or recklessly and/or negligently disregarded the wrongs complained of herein, and are therefore not disinterested parties:

(a) In order to bring this suit, all of the directors of JNJ would be forced to sue themselves and persons with whom they have extensive business and personal entanglements, which they will not do, thereby excusing demand;

(b) The acts complained of constitute violations of the fiduciary duties owed by the Company's officers and directors and these acts are incapable of ratification;

(c) Each of the Individual Defendants authorized and/or permitted the misleading statements disseminated directly to the public, authorized and/or permitted the issuance of the misleading statements and are principal beneficiaries of the wrongdoing alleged herein, and thus could not fairly and fully prosecute such a suit even if such suit was instituted by them;

(d) Any suit by the current members of the Board to remedy these wrongs would likely expose the Individual Defendants and JNJ to further violations of, *inter alia*, the securities laws that would result in civil actions being filed against one or more of the Individual Defendants; thus, they are hopelessly conflicted in making any supposedly independent determination whether to sue themselves;

(e) JNJ has been and will continue to be exposed to significant losses due to the wrongdoing complained of herein, yet the Individual Defendants have not filed any lawsuits against themselves or others who were responsible for that wrongful conduct to attempt to recover for JNJ any part of the damages JNJ suffered and will suffer thereby;

(f) If the current members of the Board were to bring this derivative action against themselves, they would thereby expose their own misconduct, which admissions would impair their defense of the relevant actions and greatly increase the probability of their personal liability in the relevant actions, in an amount likely to be in excess of any insurance coverage available to the Individual Defendants. In essence, they would be forced to take positions contrary to the defenses they will likely assert in the relevant actions. They will not do this. Thus, demand is futile; and

(g) If JNJ's current and past officers and directors are protected against personal liability for their acts of mismanagement, abuse of control and breach of fiduciary duty alleged in this Complaint by directors' and officers' liability insurance, they caused JNJ to purchase that insurance for their protection with corporate funds, *i.e.*, monies belonging to the stockholders of JNJ. But due to certain changes in the language of directors' and officers' liability insurance policies in the past few years, the directors' and officers' liability insurance policies covering Defendants in this case contain provisions that eliminate coverage for any action brought directly by JNJ against these Defendants, known as, *inter alia*, the "insured versus insured exclusion." As a result, if these directors were to sue themselves or certain of the officers of JNJ, there would be no directors' and officers' insurance protection and thus, this is a further reason why they will not bring such a suit. On the other hand, if the suit is brought derivatively, as this action is brought, such insurance coverage exists and will provide a basis for

JNJ to effectuate recovery. If there is no directors' and officers' liability insurance at all then the current directors will not cause JNJ to sue them, since they will face a large uninsured liability.

Defendants Ignored Red Flags in Connection with JNJ's Multiple Legal Violations

121. JNJ's Board consciously ignored their fiduciary duties by refusing to acknowledge numerous "red flags" that put the Individual Defendants on notice of possible wrongdoing.

122. As far back as 2003, when JNJ received subpoenas in connection with off-label marketing of Topamax and Risperdal, the Board was on notice that the Company may have been engaging in illegal activity.

123. For instance, on at least five different occasions, JNJ publicly announced that the federal government was investigating certain off-label practices.

124. Accordingly, the Board had the duty to also investigate these practices, eliminate them and ensure that JNJ's internal controls were adequate in stopping, *inter alia*, illegal off-label marketing.

125. Furthermore, the Board was on notice that certain production facilities were not in compliance with FDA standards. The Board ignored and/or approved JNJ's continued lax internal controls to prevent another damaging recall.

COUNT I

(Derivatively on Behalf of JNJ Against Weldon, Coleman, Cullen, Johns, Lindquist, Mulcahy, Mullin, Perez, Prince and Satcher for Violation of the Exchange Act §14(a) and Rule 14a-9)

126. Plaintiff incorporates by reference and realleges each and every allegation set forth above as though fully set forth herein.

127. At all relevant times, Section 14(a) of the Exchange Act was in full force and effect and provides:

> It shall be unlawful for any person, by the use of the mails or by any means or instrumentality of interstate commerce or of any facility of a national securities exchange or otherwise, in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors, to solicit or to permit the use of his name to solicit any proxy or consent or authorization in respect of any security (other than an exempted security) registered pursuant to Section [12] of this title [15 U.S.C. § 78l].

15 U.S.C. § 78n(a).

128. Rule 14a-9 promulgated under Section 14(a) provides, in relevant part:

> No solicitation subject to this regulation shall be made by means of any proxy statement, form of proxy, notice of meeting or other communication, written or oral, containing any statement which, at the time and in the light of the circumstances under which it is made, is false or misleading with respect to a material fact, or which omits to state any material fact necessary in order to make the statements therein not false or misleading or necessary to correct any statement in any earlier communication with respect to the solicitation of a proxy for the same meeting or subject matter which has become false or misleading.

17 C.F.R. § 240.14a-9(a).

129. The Proxy Statements omitted that, among other things:

a. JNJ was engaging in a scheme to market multiple products off-label; and

b. JNJ was exposed to substantial liability because of an impending recall.

130. The material omissions caused injury to Plaintiff and the Company by exposing JNJ to substantial damages.

COUNT II

(Breach of Fiduciary Duties of Care, Loyalty and Good Faith Against All Defendants)

131. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

132. Individual Defendants owed and owe the Company fiduciary obligations. By reason of their fiduciary relationships, the Individual Defendants owed and owe JNJ the highest obligation of good faith, fair dealing loyalty and due care.

133. The Individual Defendants violated and breached their fiduciary duties of loyalty, reasonable inquiry, oversight, good faith and supervision as alleged herein.

134. Each of the Individual Defendants had actual or constructive knowledge of the wrongdoing alleged herein. As such, the Individual Defendants' actions could not have been a good faith exercise of prudent business judgment to protect and promote JNJ's corporate interests.

135. As a direct and proximate result of the Individual Defendants' failure to perform their fiduciary obligations, JNJ has sustained significant damages. As a result of the misconduct alleged herein, the Individual Defendants are liable to JNJ.

136. Plaintiff on behalf of JNJ has no adequate remedy of law.

COUNT III

(Breach of Fiduciary Duty of Disclosure)

137. Plaintiff repeats and realleges the preceding allegations as if fully set forth herein.

138. The Individual Defendants have already caused materially misleading and incomplete information to be disseminated to JNJ's public shareholders. The Individual Defendants had an obligation to be complete and accurate in their disclosures.

139. JNJ's Proxy Statements and other public statements fail to disclose material financial information, including financial information and information necessary to prevent the statements contained therein from being misleading.

140. The misleading omissions and disclosures by the Individual Defendants concerning information and analyses presented to and considered by the Board and its advisors in connection with, *inter alia*, JNJ's pharmaceutical marketing efforts harmed shareholders, by preventing them from making a fully-informed decision about their holdings in JNJ.

141. Plaintiff lacks an adequate remedy at law.

JURY DEMAND

147. Plaintiff demands a trial by jury for all applicable counts.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment as follows:

A. Judgment against the Individual Defendants and in favor of JNJ for the amount of damages sustained by JNJ as a result of the Individual Defendants' misconduct alleged herein as determined at trial;

B. Directing JNJ to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with applicable laws and to protect JNJ and its shareholders from a repeat of the damaging events described herein, including, but not limited to, putting forward for shareholder vote resolutions for amendments to JNJ's By-Laws or Articles of Incorporation and taking such other action as may be necessary to place before shareholders for a vote the following Corporate Governance Policies:

1. a proposal to strengthen the Board's supervision of operations and develop and implement procedures for greater shareholder input into the policies and guidelines of the Board;

2. a provision to permit the shareholders of JNJ to nominate at least three candidates for election to the Board;

3. a proposal to better manage and disclose JNJ's marketing practices; and

4. to appropriately test and then strengthen the internal audit and control functions.

C. Extraordinary equitable and/or injunctive relief as permitted by law, equity and state statutory provisions sued hereunder, including attaching, impounding, imposing a constructive trust on or otherwise restricting the Individual Defendants' assets so as to assure that Plaintiff on behalf of JNJ has an effective remedy;

D. Awarding to Plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and

E. Granting such other and further relief as the Court deems just and proper.

Dated: June 18, 2010

Respectfully submitted,

/s/ Natalie Finkelman Bennett
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Counsel for Plaintiff

VERIFICATION

I, Walter E. Ryan Jr., hereby declare under penalty of perjury that:

1) I am a plaintiff in the above referenced case; and

2) I have read the foregoing Derivative Complaint and know the contents thereof and the same is true as of my knowledge except as to those matters therein stated upon information and belief, which I believe are true.

Walter E. Ryan Jr.

Dated: 6/17/2010